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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/802,906   | 03/17/2004  | Gary K. Michelson    | 101.0058-03000      | 5309             |
| 22882  | 7590        | 10/31/2006           | EXAMINER            |                  |
| MARTIN & FERRARO, LLP<br>1557 LAKE O'PINES STREET, NE<br>HARTVILLE, OH 44632 |             |                      | SHAFFER, RICHARD R  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3733                |                  |

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/802,906             | MICHELSON, GARY K.  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Richard R. Shaffer     | 3733                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/30/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Specification*

The amendment to the title filed on August 30<sup>th</sup>, 2006 is acknowledged and accepted by the examiner.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites the limitation "said first and second pairs of bone screw receiving holes" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-10, 13-16, 18-29, 31, 35 and 37-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Caesar (US Patent 2,825,329).

Caesar discloses a device (**Figures 1-3**) comprising: a low profile plate (**150**) with a flat (along a line extending along the length) base; the plate along the width

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having at least in part both a curve (taking a significant amount) and flat (taking a very small amount) portion; at least two bone screw receiving holes (156) receiving bone screws (158) arranged side-by-side; a locking element (140) capable of locking the screws (158) either through the use as shown in **Figures 1-3** or can also merely cover the top of plate (150) and be rotated, slid, etc into and out of alignment for allowing the screws through holes (156); locking element (140) having a circular head (142) with a cut-out (as seen in **Figure 2**).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30, 32-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caesar.

Caesar discloses all of the claimed limitations except for the use of a second locking element and thereby a second pair of bone screw receiving holes and making the device with a fusion promoting substance such as bone or bone morphogenetic protein.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided for an additional locking element and plate should more than one fracture require fixation.

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It would have further been obvious to one having ordinary skill in the art at the time the invention was made to use fusion promoting substances such as bone and bone morphogenetic protein (both well known in the art) to enhance bone healing.

### ***Double Patenting***

The following patents and patent applications have been considered for double patenting in the examination of this application:

#### **Patents:**

- 6,936,050   - 6,926,718   - 6,454,771   - 7,044,952   - 6,527,776   - 6,193,721  
- 6,936,051   - 6,398,783   - 7,041,105   - 7,077,844   - 7,118,573   - 6,383,186  
- 6,416,528   - 6,428,542   - 6,592,586   - 6,616,666   - 6,620,163   - 6,712,818  
- 6,916,320   - 6,969,390   - 7,074,221   - 7,097,645   - 7,112,202   - 7,115,130

#### **Applications:**

- 10/926,734                      - 11/110,161                      - 11/128,556

Previously, applicant filed a terminal disclaimer for 6,139,550, which has been approved. Another patent, 6,592,586 was incorrectly rejected under double patenting and after additional review was deemed to be directed to an independent and distinct species.

The following rejection is administered after extensive review of all of the above patents and applications, of which only a selection are deemed to be double patenting.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

claims 1-185 of U.S. Patent No. **7,118,573**

claims 1-160 of U.S. Patent No. **7,044,952**

claims 1-227 of U.S. Patent No. **7,041,105**

claims 1-220 of U.S. Patent No. **6,527,776**

claims 1-173 of U.S. Patent No. **6,193,721**

claims 1-39 of U.S. Patent No. **6,936,051**

claims 1-117 of U.S. Patent No. **6,398,783**

in view of Reisberg (US Patent 5,468,242).

#### **Comparison of Current Application against Conflicting Patents:**

**'573 Patent:** This patent is claiming a **concave bottom surface** instead of a **convex/flat surface**; specifies at least **one bone screw receiving hole** instead of **two**; and in regard to the **locking mechanism** (as defined in claims 23-33) again specified at

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least **one**, instead of **two bone receiving holes**. Clearly, at “least one” makes a claim of “at least two” obvious. It is merely a more restricted form already claimed as possible in the ‘573 patent. The teaching of concave to convex/flat will follow once all summaries have been given.

‘**952 Patent**: This patent again claims **concave** instead of **convex/flat**; specifies again at least **one bone screw receiving hole** instead of **two**; and specifies the locking element covering at least two bone screws however (thereby covering at least two bone screw holes). Again, clearly “at least one” obviates the condition of “at least two” in relation to the bone receiving holes, especially when at least two is required to meet the limitation of the locking element.

‘**105 Patent**: Again, **concave** instead of **convex/flat**; specifies again at least **one bone screw receiving hole** instead of **two**; a lock for at least two bone screws (thereby two bone receiving holes).

‘**776 Patent**: **Silent** as to curvature of plate instead of **convex/flat**; locking element for at least two bone screws (thereby two bone receiving holes).

‘**721 Patent**: **Concave** (in dependent claims, e.g. 7, 10), **Silent** in independent claims (1, 28) instead of **convex/flat**; locking element for covering first and second bone screw receiving holes.

‘**051 Patent**: **Concave** instead of **convex/flat**; lock for at least two bone screw receiving holes.

‘**783 Patent**: **Concave** instead of **convex/flat**; lock for at least two bone screws (inserted in two bone screw receiving holes).



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Reisberg teaches (**Column 1, Lines 5-20**) that having implants that conform to the bone surface/anatomical shape (e.g. convex, flat, and concave) is desired. One having ordinary skill in the art at the time the invention was made would have developed a device that either was pre-shaped or moldable to conform to the anatomy to provide for a low profile fit that would 1) minimize external visualization of implant and therefore embarrassment of patient 2) irritation from inflammation 3) allow fixation members (screws, tacks, pins, etc) to have greater holding force (instead of having a significant portion hanging out of the bone). Therefore, applicant's numerous patents attempting to differentiate bone plates on the premise of concave vs. convex/flat are not novel. The mere shaping of an interface surface to conform to the intended bone to which it is to be placed is already known to be desired and beneficial.

Any additional difference between the previous patents and the current application lies in the fact that the claims (taking into account dependent claims in several) in the patents include more elements and are thus more specific. The inventions therefore define a "species" of the "generic" invention of claim 7. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).



Claims 7-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1-72 of copending Application No. **10/926,734**

claims 1-62 of copending Application No. **11/128,556**

in view of Reisberg. As discussed in the patent section, applicant is merely reciting a concave base section with one application being "at least one" again with the other being "at least two" in regard to the bone receiving holes. Each one recites at least "two bone screws" in regard to a locking element

This is a provisional obviousness-type double patenting rejection.

### ***Response to Arguments***

Applicant's arguments with respect to claims 7-41 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer  
October 26<sup>th</sup>, 2006



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER